IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1978 MICHAEL RODAK, JR., CLERK

No. 78-429

WILLIAM and MAXINE HASTE, Petitioners

V.

AMERICAN HOME PRODUCTS CORPORATION, Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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OF CERTIORARI TO THE UNITED STATES COURT
OF APPEALS FOR THE TENTH CIRCUIT

## OPINION BELOW

The Court of Appeals' Opinion has now been published and is reported, Haste v. American Home Products Corp., 577 F.2d 1122 (10th Cir. 1978).

## STATEMENT OF THE CASE

Petitioners' statement of the case is slanted, argumentative and omits important circumstances established by the evidence, necessitating a statement by Respondent, which can probably be best done by quoting from Respondent's Appeal

Brief and Reply Brief, which were not challenged in the Court of Appeals:

> "In 1970 Mr. and Mrs. William Haste, Meeteetse, Wyoming, ranchers, running some 250 head of Santa Gertrudis type cattle, had a problem when some of their cows became afflicted with what their veterinarian, Dr. Humphreys, diagnosed as anaplasmosis. They talked to him about vaccinating with Anaplaz, a vaccine dispensed by Defendant, if they had more trouble in the future. advised of the possibility Neonatal Isoerythrolysis in calves from the use of the vaccine and they did nothing about vaccinating at that time. In May of 1971 Hastes had Dr. Humphreys vaccinate two of their bulls with Anaplaz. Later that year they bought 45 head of Angus cows from an area infested with anaplasmosis and after they had lost 28 cows from that disease, they secured Anaplaz vaccine from Dr. Roberts, another of their 'regular veterinarians', who also explained to them the possibility of the side effects of NI in calves of the vaccinated cows. They vaccinated cows themselves, after reading the warning and directions on and in the containers, each package bearing on the outside a prominent caution sign reading 'Caution; See Enclosed Leaflet Concerning Possible Risk In Vaccinating Breeding Females.' (Ex. L, R. Vol. VII, Ex. App. p. 122). The Hastes also read the cautionary

statement on the <u>inside</u> of the package.

"Thereafter they lost no cows from anaplasmosis, but after two booster shots of vaccine, the last of which was secured in 1973 from another of their 'regular veterinarians', Dr. Lester, a number (39) of their calves died of a disease which was diagnosed as NI..."

"Plaintiffs had a marginal operation of crossbreed cattle (Santa Gertrudis), which were particularly susceptible to anaplasmosis."

"Anaplaz, a vaccine against anaplasmosis could be procured only from veterinarians all of whom had been advised by American Home that the vaccine might cause NI in calves of vaccinated animals. ..."

"The vaccine which Plaintiffs purchased had a prominent red warning on the outside and also had a clear understandable warning on the inside that detailed the risk to one using the product. The Hastes admitted that they read and understood such warning."

## SUMMARY OF ARGUMENT

l. Petitioners' "finding of fact unproven" argument was not raised below and is specious. The Tenth Circuit adopted the Trial Court's supported finding that Anaplaz, procurable only

through veterinarians, should be governed by the "prescription drug" doctrine.

- 2. The Tenth Circuit decision by extending the "prescription drug" doctrine to Anaplaz, because it is dispensed in a manner similar to the sale of prescriptions, is not in conflict with decisions of other circuits or with federal statutes regarding "prescription drugs." No circuit has held that the "prescription drug" doctrine applies only to those products defined in 21 U.S.C. §353.
- 3. There is no conflict among the decisions of the circuit courts regarding the effect of advertising on the duty to warn. Also this argument was not raised by Petitioners below. No circuit has imposed a duty to warn the public on a drug manufacturer when all physicians have been adequately warned.
  - 1. THE TENTH CIRCUIT DID NOT MAKE A FINDING OF FACT UNPROVEN IN THE RECORD.

Petitioners criticize the Court of Appeals for "making a finding of fact unproven in the record", saying "at the trial no substantial evidence of any sort

was presented to prove that Anaplaz was considered a prescription drug."

Such a criticism is unwarranted and provides no basis for a consideration of the matter by this Court for several reasons:

Respondent on page 10 of its (a) brief to the Court of Appeals said, "Judge Winner in his opinion has agreed with Defendant that Anaplaz is to be considered a prescription drug." (R. Vol. IV, p. 1352, App. p.32) Petitioners did not challenge this as being unsupported by the evidence, in either their briefs or oral argument to the Court of (Their original Brief relates Appeals. only to damages. For their Reply Brief see Appendix pages 1-35). They cannot raise the question now.

It is well established that this Court will refuse to consider claims not made below. 32 Am. Jur. 2d Federal Practice & Procedure §297; 4 C.J.S. Appeal and Error §228; Youakim v. Miller, 96 S. Ct. 1399 (1976); California v. Taylor, 353 U.S. 553, 557 (1957); Lawn v.

U.S., 355 U.S. 339, 362-363 (1957); Michel v. Louisiana, 350 U.S. 91, 100 L.Ed. 83, 76 S. Ct. 158 (1955), reh. den. 350 U.S. 955, 100 L.Ed. 831, 76 S. Ct. 340 (1956); Beauharnais v. Illinois, 343 U.S. 250, 96 L.Ed. 919, 72 S.Ct. 725 (1951), reh. den. 343 U.S. 988, 96 L.Ed. 1375, 72 S. Ct. 1070 (1952); Desper v. Starved Rock Ferry Co., 342 U.S. 187, 96 L.Ed. 205, 72 S. Ct. 216 (1951), reh. den. 342 U.S. 934, 96 L.Ed. 695, 72 S. Ct. 374 (1952); Helvering v. Fuller, 310 U.S. 69, 84 L.Ed. 1082, 60 S. Ct. 784 (1939); Kay v. United States, 303 U.S. 1, 82 L.Ed. 607, 58 S. Ct. 568 (1937); Lanasa Fruit S. S. & Importing Co. v. Universal Ins. Co., 302 U.S. 556, 82 L.Ed. 422, 58 S. Ct. 371 (1937); Sonzinsky v. United States, 300 U.S. 506, 81 L.Ed. 772, 57 S. Ct. 554 (1936); Helvering v. Tex-Penn Oil Co., 300 U.S. 481, 81 L.Ed. 755, 57 S. Ct. 569 (1936).

(b) The statement of Judge Winner "Moreover, for the purposes of resolution of this case, I accept Defendants' arguments that Anaplaz and its sale should be treated as

the sale of a prescription drug, albeit the record is short a few elements of proof of a true prescription drug." [Emphasis supplied] (Petitioner's App. p.42)

is, in reality a finding of fact, based on evidence that Anaplaz is sold under circumstances which are sufficient to invoke the "prescription drug" doctrines. The Tenth Circuit did no more than repeat this finding.

Petitioners have failed to consult the record when they say,

"At the trial no substantial evidence of any sort was presented to prove that Anaplaz was considered a prescription drug."

Dr. Roberts when asked by Judge Winner, "Did you write a prescription for it?" answered, "No. It is not required to write a prescription for it." (R. Vol. X, p. 40), and at another point said, "I don't feel that I have to write a prescripton to sell this product" (R. Vol. X, p. 41). However, at another time he conceded that the Hastes could not purchase the vaccine themselves from Fort

Dodge, as he said, "because this is sold to veterinarians only." (R. Vol. X, p. 45).

Dr. Lester, another of the Hastes' "regular veterinarians", when asked, "Dr., what kind of a drug is Anaplaz, what kind of a vaccine is Anaplaz according to your knowledge or information?" answered "It is a prescription drug." [Emphasis supplied] (R. Vol. X, p. 105) Dr. Searl, a veterinarian employed by Defendant, when asked about the restrictions with respect to Anaplaz answered, "Anaplaz is a veterinary prescription biological product." When counsel queried, ". . . at least that is what you think it is", Dr. Searl responded, "That's what I know it is, and it is sold only to licensed veterinarians and to no one else, including M.D.'s. And as with a prescription biological, there are requirements and obligations when he gets it as to what he does with it." (R. Vol. XIII, pp. 182, 183).

The Anaplaz carton and package insert clearly stated:

"Warning: Restricted by the U.S. Department of Agriculture to use by or on the order of a licensed veterinarian." (Ex. L, R. Vol. VII; Ex. 24, R. Vol. VI)

As indicated on the package and insert, the Department of Agriculture restricts the use of Anaplaz to veterinarians in much the same way that the Food and Drug Administration restricts use of human prescription drugs to physicians. In both cases it is clear that the purpose of the restrictions is to prevent the public at large from having direct access to those medical products which are too complex for lay use and for which the layman does not have the training or knowledge to know when, where and how to use or not use the product.

Thus, there was before the trial Court substantial evidence that Anaplaz was a prescription type drug sold only on the order of a veterinarian, and the statement of Judge Winner, when fairly interpreted, was a fully supported finding of fact that ". . . Anaplaz and its sale should be treated as the sale of

a prescription drug." (Petitioners' App. p.42)

(c) If the sentences of the Circuit Court opinion are not isolated in the analysis, they fairly reflect the trial Court's finding:

> "The trial Judge acknowledged that the drug was a 'prescription drug.' The Anaplaz vaccine was only available from veterinarians, and Plaintiffs obtained the dosages here concerned from their veterinarians. In this aspect of the case, it makes no difference whether the drug was compounded by the defendant or by a pharmacist. Since it is a prescription drug, the doctrines applicable thereto must be applied. and the trial Court was in error in not doing so." Haste v. American Home Products Corp., 577 F.2d 1122, 1124, (10th Cir. 1978).

> "The records shows the typical 'prescription drug' sequence of events: The Hastes had livestock exposed to anaplasmosis from new stock they had brought into the herd; they became interested in Anaplaz from the ads in the livestock magazines; they consulted their 'regular' veterinarians (two of them) before making a decision as to what to do; they received typical medical advice; they balanced the risks; they decided to have the

Anaplaz ordered by Dr. Roberts (a veterinarian was the only source); they received it from him; they read and understood the leaflets, and used it. Their veterinarians were knowledgeable on the problem, and were well advised by defendant as to the risks. In this chain or sequence of events, the defendant discharged its duty to plaintiffs by the warnings to the veterinarians." Haste v. American Home Products Corp., 577 F.2d 1122, 1125 (10th Cir. 1978).

It is submitted that the West headnote 2 well summarizes the Court of Appeals holding:

> "Products Liability. Where cattle vaccine in question was only available from veterinarians, and cattle breeders obtained dosages for their herd from their veterinarians, vaccine was "prescription drug," of whether it regardless compounded by manufacturer or by pharmacist, and prescription drug doctrines were applicable in products liability action arising out of use of vaccine." Haste v. American Home Products Corp., 577 F.2d 1122 (10th Cir. 1978)

Petitioner's did not raise the point before the Court of Appeals, so that the sufficiency of the evidence to support Judge Winner's acceptance could there

have been determined. They cannot now avoid the fact that both the trial Court and the Court of Appeals have held that the vaccine, because it could be procured only through doctors, should be governed by the doctrines applicable to prescription drugs.

2. THE TENTH CIRCUIT DECISION
IS NOT IN CONFLICT WITH
DECISIONS OF OTHER CIRCUITS OR
21 U.S.C. §353(b)(2).

It should be noted initially that Petitioners base their second and third grounds for review upon a purported conflict of opinions among the Circuit Courts of Appeal. However, all cases mentioned by Petitioners were brought as diversity actions involving application of the law of California, Illinois, Montana, Pennsylvania, South Dakota or Texas. In this action, the Tenth Circuit acknowledged that Wyoming law is controlling and that the matter must be

considered in light of such Wyoming decisions as Maxted v. Pacific Car & Foundry Co., 527 P.2d 832 (Wyo. 1974) and Colorado Serum Co. v. Arp, 504 P.2d 801 (Wyo. 1972). Petitioners have not cited a conflict between the Tenth Circuit Opinion and other reported cases involving Wyoming law. The decision of the Tenth Circuit is supportable as a matter of Wyoming state law, as Respondent herein contends, and thus any "conflict" (which Respondent denies in the argument below) may be the result of differing state laws and does not warrant the extraordinary relief sought by Petitioners, Ruhlin v. New York Life Ins. Co., 304 U.S. 202, 58 S. Ct. 860, 82 L.Ed. 1290 (1938). Furthermore, Petitioners do not raise important questions of federal law nor any issues of constitutional dimension. Petitioners have cited no conflict between the Tenth Circuit Opinion and decisions of this Court. Petitioners merely seek review to obtain a reversal of the Tenth Circuit Opinion for their own private benefit.

The Court of Appeals actually adopted the finding of Judge Winner that, "Anaplaz and its sale should be treated as the sale of a prescription drug" (Petitioners' App. p. 42) [Emphasis supplied] and stated as its reason the fact that "The Anaplaz only available from vaccine was veterinarians, and Plaintiffs obtained the concerned dosages here from their veterinarians." Haste v. American Home Products Corp., 577 F.2d 1122, 1124 (10th Cir. 1978).

Neither Court, by fair analysis, said that Anaplaz was a prescription drug within the meaning of 21 U.S.C. §353(b), nor could they have properly done so, since that statute specifically limits the "prescription by physician" to "the drug intended for use by man . . ." [Emphasis supplied]. Certainly Congress adopting 21 U.S.C. §353(b)(2) did not intend it to apply to animals.

A fair reading of Judge Winner's Opinion and that of the Court of Appeals indicates that neither meant to say that Anaplaz was in fact a prescription drug

but rather that it bore the characteristics of a prescription drug, which circumstance justified its being treated as one, since it could be procured only from a doctor, familiar with diseases, their prevention or cure, and familiar with the circumstances of his patients who may have need of the drug.

It must also be borne in mind that Dr. Roberts was not the only veterinarian who testified concerning Anaplaz as a prescription drug and that Dr. Lester said unequivocally, "It is a prescription drug."

Also, as was pointed out at page 6 of Respondent's Court of Appeals Reply Brief, which was unchallenged by Petitioners, Dr. Searl testified that the "Dear Doctor" warning letters were sent to all veterinarians (R. XIII, p. 180). There is a presumption that they were received, First National Bank v. Ford, 216 P. 691, 30 Wyo. 110 (1933), and the District Court adopted this presumption (Petitioners' App. p. 42). That presumption is unrebutted here.

Further, Dr. Humphreys discussed the "Dear Doctor" letters in his testimony (R. Vol. X, p. 23) and indicated that he had seen these as well as like publications containing warnings. The District Court found that these letters to veterinarians "... recognized the risk of N.I.,..." (Petitioners' App. p. 36).

In this light, discussion of the cases cited by Petitioners in this section is relevant and desirable.

Singer v. Sterling Drug, Inc., 461 F.2d 288 (7th Cir. 1972) was a case where the drug manufacturer failed to give notice of the danger to the doctor, who gave an oral prescription to pharmacists, and where there was no evidence of a warning to the user, except that she stay out of the sun. Here there was positive evidence that the veterinarians were warned, that they relayed the warnings to the Hastes and additionally the Hastes read the written warnings on and in the vaccine packaging.

Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. CA 1968) dealt with a human vaccine for polio, dispensed

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in mass clinics where individual consultations between patient and doctor were non-existent. The Court held that under such a situation there was no sufficient warning to a customer who had no contact with a physician who had received the warning. However, that Opinion contained a statement at page 131 which is significant in the present case:

"When drugs are sold over the counter to all comers warnings normally can be given by proper labeling."

The Hastes admitted the reading of the warnings on the outside of the Anaplaz package as well as that contained in the inserts. (R. Vol. XI, pp. 50, 51)

In Reyes v. Wyeth Laboratories Inc., 498 F.2d 1264 (5th Cir. 1974), a case which also dealt with oral polio vaccine, the Court affirmed a judgment for the plaintiff citing Davis v. Wyeth Laboratories of the 9th Cir., supra, holding that where the laboratory marketed unavoidably unsafe trivalent oral polio vaccine and failed to provide parents of infants with either warning of risk or

individualized medical judgment it was liable for failing to warn. Both of the Wyeth cases are consistent with the holding of the Court of Appeals in Hastes.

Petitioners' conclude that, on the strength of the Davis case, "if the drug is not dispensed by filling and refilling a prescription, warning must be given to the consumer directly by the most reasonable means available to adequately inform the user of the risks." The Court of Appeals decision, as already pointed out, noted the Hastes read and understood the written warnings which the vaccine package contained, and as to that from the veterinarians stated succinctly:

trial Judge considered and evaluated the warnings given Plaintiffs by the veterinarians, and found them minimal. However, the record shows that the veterinarians were well aware of the risks. had adequate advice as to the risks from Defendant. These were the 'warnings' which are significant for prescription drugs, and thus controlling here. There were no fact questions as to these warnings."

Certainly the Haste decision followed, rather than departed from the holding in Davis v. Wyeth.

The line of cases which reflect the "prescription drug" doctrine do not focus on whether the product is in fact a "prescription drug" within the meaning of the federal statutes and regulations, nor on whether the sale of the drug is administered strictly through doctor's prescription and subsequent purchase from a pharmacist. The key factor cited by the courts is the contact between the consumer and a licensed practitioner who has received warnings from the manufacturer and who is familiar with the circumstances of his patients. The one-to-one contact permits the licensed practitioner to give sound advice to the consumer regarding a decision within his field of practice.

"Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in

light of the physician's knowledge of his patient's needs and susceptibilities." Davis v. Wyeth Laboratories, Inc., 130 (9th Cir. 1968).

"In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a sideeffect in some patients, and is advised of the symptoms normally accompanying the side-effect, there is an excellent chance that injury to the patient can be avoided." Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966)

"The universal view is that a warning in a prescription drug should be made to the prescribing practitioner, because he is in the theoretical position of being able to evaluate and balance the dangers of the drug against the utility from the drug." Dixon, Drug Product Liability, \$9.02[2].

Certainly non-prescription drugs can be dispensed under circumstances in which a "learned intermediary" is involved, and can therefore fall into the category of "prescription drugs" for the purpose of determining to whom the manufacturer's warning should be directed. This has

been recognized in existing case law, and therefore the Tenth Circuit opinion is not in conflict with other opinions by extending the "prescription drug" doctrine to products which are not prescription drugs under federal statutory definitions. For example, in Heirs of Fruge v. Blood Services, 365 F. Supp. 1344 (W.D.La. 1973), the court noted at page 1350 that blood products are ". . . analogous to 'prescription only' drugs . . . " and proceeded to apply the general rule that, in situations where a product can be obtained only through a physician, only the physician need be warned. Similarly, in Gravis v. Parke-Davis & Co., 502 S.W.2d 863 (Tex. App. 1973), the court noted that the product involved therein, an anesthetic, was available only upon order of a physician, and went on to hold:

"The laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry."

(Emphasis supplied) Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. App. 1973).

It is equally clear that when the "learned intermediary" is not involved in a sale of a drug to consumers, the mere fact that the product involved is a prescription drug within the meaning of federal statutes will not permit the product's manufacturer to invoke the protection of the "prescription drug" doctrine. In Davis, supra. and Reyes, supra., the Sabin Type III oral polio vaccine was indeed a prescription drug meaning of the federal within the statutes, but nevertheless a warning to the physician was insufficient where the physician did not fill the role of "learned intermediary."

The Tenth Circuit Opinion likewise focused on the presence of the ". . . typical 'prescription drug' sequence of events . . .", Haste v. American Home Products Corp., 577 F.2d 1122, 1125 (10th Cir. 1978). The Tenth Circuit Opinion is therefore in harmony with the other cases

which form the basis of the "prescription drug" doctrine, and there exists no conflict among the circuits which would warrant the issuance of a writ of certiorari.

3. THERE IS NO CONFLICT AMONG
THE TENTH CIRCUIT DECISION AND
THE DECISIONS OF OTHER CIRCUITS
AND STATE COURTS IN EVALUATING
THE DUTY TO WARN WHERE ADVERTISING IS INVOLVED.

Petitioner erroneously claims there is a conflict among the circuits and state courts concerning the effect of advertising on the duty to warn. Petitioner also cites a conflict between the Tenth Circuit decision and federal law.

It should again be noted that the federal laws regarding advertising of prescription drugs, 21 U.S.C. §352(n) and 21 C.F.R. §202.1(e), are not applicable to Anaplaz because it is not a prescription drug within the meaning of 21 U.S.C. §353. Thus no actual conflict or erroneous ruling of law exists in this regard which would call for review by this Court. Furthermore, Petitioners'

argument regarding federal statutory advertising requirements was not raised in the Court below, being nowhere found in the Petitioners' Tenth Circuit Reply Brief attached hereto at Appendix pp. 1-35, and should not be considered by this Court.

The cases cited by Petitioners for the proposition that a seller's overpromotion of a drug mitigates the warnings otherwise given to practitioners are not on point and are not in conflict with the opinion of the Tenth Circuit Court of Appeals. In all four cases (Love v. Wolf, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (Ct. App. 1967); Incollingo v. Ewing, 444 Pa. 263, 283 A.2d 206 (1971); Stevens v. Parke Davis & Co., 107 Cal. Rptr. 45, 507 P.2d 653 (1973); and Sterling Drug v. Yarrow, 408 F.2d 978 (8th Cir. 1969)) the were dealing with situations Courts involving over-promotion of a prescription drug to a physician. The cases did not directed the involve advertising to The trial court in this action public. did not find that American Home advertising directed its to the veterinarians, but rather found that it had directed its advertising toward cattlemen, Petitioners' Appendix pp. 35, 42.

In Love v. Wolf, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (Ct. App. 1967) the Court noted at 58 Cal. Rptr. 49, 249 Cal. App. 2d 832, 833, that the doctor's state of mind is an important factor. particularly as it is affected by the drug manufacturer. The Court found that the warnings to the doctor inadequate and that the drug manufacturer was aware of the inadequacy. The Court concluded that over-promotion of the drug to the doctor was one factor in the inadequacy of the warnings. In this case, the District Court did not find that American Home gave inadequate warnings to the veterinarians, nor did it find that there was any over-promotion of the drug to the veterinarians, nor did it find that American Home was aware of any inadequacy in the warnings given to veterinarians. It should further be noted that in an earlier case involving the same parties and facts, Love v. Wolf,

266 Cal. App. 2d 378, 38 Cal. Rptr. 183, Ct. App. 1964), the Court had held that the drug manufacturer only had a duty to warn the doctor:

"Parke-Davis has no contact with the ultimate consumer of this drug, the patient. The duty, therefore, whatever its extent may be, must be a duty to warn the doctor who prescribes the drug. This would be the only effective means by which warning could help the patient." Love v. Wolf, 38 Cal. Rptr. 183, 192, 266 Cal. App. 2d 378 (Ct. App. 1964).

In <u>Incollingo v. Ewing</u>, 444 Pa. 263, 283 A.2d 206 (1971), again there was over-promotion of the drug to the doctor, but there was no advertising to the public. The court held that ". . . the warning required is not to the general public or to the patient, but to the prescribing doctor." The Court went on to find that the warnings given doctors were inadequate in light of the manufacturer's knowledge and were further nullified by the representations of "detail men" which amounted to over-promotion of the drug. Again, distinguishing the present case

from <u>Incolling</u>o are the absence of a finding that advertising was directed to the physician, and the absence of a finding that warnings actually given to the veterinarians were inadequate.

In Stevens v. Parke-Davis & Co., 107 Cal. Rptr. 45, 507 P.2d 653 (1973) the Court found that warnings to doctors were inadequate because they had been "watered down" by over-promotion of the drug to the doctors. Again, no duty to warn the public was involved, but rather a finding that a duty to warn the doctors had not been fulfilled. In the present case, the District Court did not find that American Home had failed to adequately warn the veterinarians.

In Sterling Drug v. Yarrow, 408 F.2d 978 (8th Cir. 1969) the Court repeated the standard "prescription drug" doctrine that a warning need only be given to doctors. However, again the drug manufacturer's "detail men" failed to point out the side effects of the drug, and the Court found that such failure amounted to a failure to give adequate warning to the

doctors of the possible side effects. Again, no advertising was directed to the public and no duty to warn the public was established.

The District Court held here that there is a duty to warn the consumer directly when advertising is aimed at the consumer:

"I think that the direct sales effort (even though the product was channeled through veterinarians) imposed on Defendant a duty to warn the ultimate consumer before he spent his money on the purchase." (Petitioners' App. 43, 44.)

The Tenth Circuit held that it was error to ignore the warnings given to veterinarians and to impose such a duty:

> "The Trial Court was in error in holding that the contents of the advertisements of Anaplaz in the various livestock publications are controlling on the warning issue, and thus override the practical considerations which arise from the requirement that the consumer purchase the vaccine only from veterinarians, and override the 'prescription established drug' doctrines." Haste v. American Home Products Corp., 577 F.2d 1122, 1125 (10th Cir. 1978).

American Home in its Appeal Brief stated that the duty imposed by the District Court is unsupported in the law. In the Tenth Circuit, Petitioner was unable to point out any law in support of such a duty. The cases now cited by Petitioner can only stand for the proposition that advertising directed to physicians must be considered in determining the adequacy of warnings given to the physician, and they cannot be considered as support for the proposition that there is an absolute duty to warn consumers in advertising directed to the consumer when adequate warnings have been given to physicians. Here all of the advertising directed to the consumers advised them to first consult their veterinarian; the veterinarians were warned by American Home and these warnings were also relayed to the Petitioners when they consulted with their "regular veterinarians" regarding vaccinating with Anaplaz.

## CONCLUSION

The Tenth Circuit Court of Appeals did not make a "finding of fact unproven in the record," nor is its decision in

conflict with the decisions of other circuits or with federal law. The Petitioners have raised spurious arguments in
order to obtain review by this Court of
their private grievance which involves no
questions of federal or constitutional
import. The Petition for a Writ of
Certiorari should be denied.

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6 October 1978

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

Nos. 76-2015 and 76-2016

WILLIAM HASTE and
MAXINE HASTE,
Plaintiff-Appellant )
and Cross-Appellee, )
vs. )
AMERICAN HOME PRODUCTS
CORPORATION,
Defendant-Appellee )
and Cross-Appellant.)

REPLY BRIEF OF APPELLANT AND CROSS-APPELLEE

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August 10, 1977 App. p. 1

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### UNITED STATES COURT OF APPEALS

### TENTH CIRCUIT

Nos. 76-2015 and 76-2016

WILLIAM HASTE and

MAXINE HASTE,

Plaintiff-Appellant )
and Cross-Appellee, )

vs.

AMERICAN HOME PRODUCTS )
CORPORATION,

Defendant-Appellee )
and Cross-Appellant.)

# REPLY BRIEF OF APPELLANT AND CROSS-APPELLEE

This reply brief is submitted in rebuttal on the issues presented in the opening brief of Appellee and Cross-Appellant. Appellant and Cross-Appellee responds first to the Appellee and Cross-Appellant's rebuttal regarding the issues of Damages and then to the issues regarding Cross-Appellant's challenge of the finding of liability in the trial court.

Parties will be referred to by name or as designated Plaintiff or Defendant in the trial court.

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All citations to the Appendix prepared in this case shall be in this form [App. p. 366, L.2]. Citation to the Prepared Exhibits will be in this form [Ex. p.616]. Citation to the Record shall be [Rec.Vol. XX p.3010, L.2]. Citation to exhibits not in the Prepared Exhibits shall be in this form [Rec.Vol. VII, Ex.198].

## ISSUES PRESENTED

- I. The trial Court erred in its computations regarding the number and value of cows sold.
- II. The trial Court erred in failing to award damages for loss to the upgrading program.
- III. The trial court erred in failing to admit Exhibits 91 and 92.
- IV. The trial court erred in failing to award for increased feed costs.
- V. The Record discloses substantial evidence of causation;
- VI. Any warnings were insubstantial, inadequate and eroded by publicity promoting the product.
- VIII. Actual and implied warranties were given by Defendant in App. p. 5

promotional literature.

## STATEMENT OF THE CASE

The Hastes would incorporate the statement of the case presented in the opening brief as if fully set out herein.

The statement of the case as presented in the Defendant's brief is objectionable in that it represents "facts" as "proven" where obvious and continuing conflict existed in the exhibits and testimony. A reading of the entire record, particularly the transcript of trial testimony, discloses that the plaintiffs and the veterinarians called by Defendant gave continually conflicting testimony regarding the conversations between them and the particulars of those conversations.

The record discloses that none of the veterinarians called by the Defendant testified to having received any of the "Dear Doctor" letters apparently sent by the Defendant. Furthermore, the testing of Anaplaz performed by outside experts has continually shown that Anaplaz causes Neonatal Isoerythrolysis (N.I.). Plaintiffs did not seek to App. p. 6

show that Anaplaz is the only cause, but that it was the cause in this case. Defendant states in its Statement of the Case that:

"To this date, it is the opinion of veterinarians and scientists who have participated in the investigations that there is not enough scientific proof to establish a cause and effect relationship between Anaplaz and N.I." (Brief of Appellee and Cross-Appellant P.7).

This totally mistates the status of the present scientific investigation and ignores the evidence presented at this trial from scientists such as Dr. Stormont and Dr. Young, the veterinarians called by the Defendant, and the United States Government as well as the Defendant itself who saw fit to include a warning in the insert indicating that there are indications that N.I. may result. Certainly at the time of trial in this matter substantial testing had been performed as testified to by Dr. Stormont and indicated by the articles of Dr. Stormont and Dr. Young. Plaintiffs invite the Court to read the record of the liability trial, specifically the

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testimony of Dr. Stormont, for evidence presented on the relationship of Anaplaz to N.I. It is evident that the Defendant is hiding its corporate head in the sand to ignore and discount the overwhelming evidence that Anaplaz has a direct relationship to the occurrence of N.I.

## ARGUMENT

Computation of cows was in error.

Plaintiffs make no argument that Defendant's exhibit U indicates that 40 cattle were not worth more than slaughter value. However, the evidence discloses that the plaintiffs gave value to the cows and estimated a life for them as indicated in their tax returns. Charlesworth indicates that these cows had no practical value as breeders. He never saw these cows or the results of their breeding. His opinion is based upon generalities of his experience and not supported by any actual evidence that the particular cattle had no value as breeders to the Hastes. There is no evidence that these cows would fail to produce viable, saleable calves.

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Furthermore. the Plaintiffs testified that due to the N.I. propensities of their brood cows they were forced to sell at slaughter prices. Mr. Haste testified that he actually received \$300.00 on an average for each cow sold for slaughter. [Mr. Haste's testimony, App. p.94, L.1-11]. The Defendant's Exhibit U indicates that the slaughter value according to Dr. Searl and Dr. Charlesworth would be \$353.00. The forced sale at the time the Hastes had to sell breeding cows in Wyoming, where no other Santa Gertrudis herds existed, caused at least a minimum loss of \$2,120.00.

11. Upgrading program damages.

Defendant states, as did the trial Court memorandum on the issue of damages, that the request for damages for losses sustained by the up-grading program was actually a request for multiple damages since before and after value of the cows was given. Yet neither Judge Winner nor the Defendant indicates how this award would be duplicatious of the other award if the before and after value of the cows is subtracted from the

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loss to the upgrading program.

Mr. Elrod testified that the Hastes entered into the upgrading program in February of 1972. This program had value to the Hastes in that, at its conclusion the Hastes would have not only a herd of cattle, but the reputation, goodwill and certification as breeders of purebred Santa Gertrudis cattle. The loss of the individual cattle at the time of the injury and the loss of breeding capacity cannot compensate fully for the loss of future profit from the termination of the involvement in this program.

This is not simply a speculative improvement of the breed but a program determined by other breeders designed to provide standards of quality and a rating procedure. All testimony indicated that cattle given a higher classification (except bulls until they were registered pure-bred) were of increasingly greater value. The program was scientifically controlled by inbreeding to achieve ultimate perfection within the Santa Gertrudis breed. There was ample evidence that the Hastes were following the program and actively App. p. 10

attempting to increase the value of the herd.

This loss was not easily calculable. However, the case law is clear that simply because the damages are difficult of ascertainment the fact finder is not relieved of the responsibility of approximating an amount for an award. [This issue was amply raised and argued in the Plaintiffs' opening brief and cases cited there will not be repeated in the interest of brevity.]

Mr. Haste's unrebutted testimony that the upgrading program itself represented a loss of \$100,000.00. As indicated in the opening brief, if the award for the lost cows and calves is subtracted from the amount representing the loss to the upgrading program there is no terrible danger that a duplication of damage would occur.

The Defendant implies that the Hastes did not pursue a course of reasonable action in failing to purchase replacement cows. The testimony regarding the plaintiffs' desparate financial condition after the N.I. problem and due to it, as well as the then existing cost

of comparable cross-bred cattle made such replacement impossible for the Plaintiffs. As the opening brief citations indicate such replacement is not necessary in situations where the burden would be too onerous.

III. Exhibits 91 and 92.

Counsel for Plaintiffs would agree with counsel for Defendant that the record of the damages trial indicates such amount of confusion and a perplexing lack of preparation on the part of Plaintiffs' trial attorneys on the issues related to damages. However, the evidence that was educed at the trial makes it abundantly clear that some form of demonstrative evidence would have been useful to clarify exactly the thrust of the Plaintiffs' damage allegations. Exhibits 91 and 92 were such exhibits and should have been admitted despite the inartful manner in which they were described and presented. The trial Court seemed overtly antagonistic to the expert economic testimony presented by the Plaintiffs and continually challenged Plaintiffs' attorneys and apparently badgered them into withdrawing one of App. p. 12

their claims.

The claim for damages to upgrading was not withdrawn and the Exhibits offered had a direct bearing on the determination of the amount of loss to that program.

IV. Increased Feed Costs.

The increased feed costs, as evidenced by the tax returns of the Plaintiffs and statements of the sickly condition of the cattle by Gene Schreibeis are ample evidence of additional damage to the Plaintiffs. The feed required to prepare the cattle for sale after the N.I. illnesses is not a multiplication or duplication of awarded damages.

This feed was in addition to that normally required. It is not reflected as part of the awarded price of the cattle. Judge Winner was remiss in not making some monetary award for this loss.

## V. Causation.

The Defendant asserts that since the written records provided to Dr. Searl by Mrs. Haste show that one calf that died of N.I. was born of a cow for which App. p. 13 no notation of vaccination with Anaplaz was made that this conclusively shows that Anaplaz did not cause the N.I. in the Haste herd.

Maxine Haste testified that all of the brood cows were vaccinated with Anaplaz vaccine [Appendix p.65, Line 9-23]. The records in evidence show that the Plaintiffs vaccinated hundreds of animals with Anaplaz as well as other These records were kept by vaccines. Maxine Haste during the course of the normal ranch routine. The finding of one mistake or omission on the part of Mrs. Haste in her record keeping is neither surprising nor dispositve of the liability issue in this case. The fact that Mrs. Haste missed only one entry out of several hundred cows is credit to her bookkeeping.

The Defendant goes to great lengths to argue that the testimony of Dr. Searl is the only probative testimony on the issue of causation. As Judge Winner noted.

"The opinion testimony is diametric as to causation. The product is new, and perhaps further App. p. 14 scientific study and research will prove defendant's experts to be right, but as the trier of fact, and based upon the expert testimony so saying, I find that the Anaplaz vaccinations of plaintiffs' herd was the proximate cause of the N.I. later discovered in those cattle."

(3) "In so finding, I am not unaware of evidence tending to show that one cow diagnosed as having N.I. was not vaccinated with Anaplaz, but I think that the preponderance of the evidence shows to causal connection between Anaplaz and N.I. That connection is surely not established beyond a reasonable doubt, but I think that the civil case test of preponderance of the evidence is met."

Plaintiffs agree that proof cannot be speculative, but in matters of expert opinion it is not uncommon that the experts differ in the interpretation of data and the methods used. The extensive testimony of Dr. Stormont, that his experiments proved that Anaplaz produces the sensitization in catle causing isoantibodies which ultimately cause N.I. in calves [Appendix p.100-116] was not controverted by comparable evidence of App. p. 15

experiments by the Defendant showing otherwise. Dr. Searl and Dr. Stormont are at odds as to the side-effects of Anaplaz. Judge Winner in weighing the evidence chose, rightly, to find that by a preponderance of the evidence Anaplaz caused N.I. in the Haste herd.

Dr. Stormont indicates that he has never encountered N.I. in a herd that was not vaccinated with Anaplaz [App. p. 117 L. 17-20]. He also indicated that he knew of no published proof that N.I. had been found in any herd that had not been vaccinated with Anaplaz [App. p.117 L. 21-24] except from Australia where they have another kind of homologous blood vaccine [App. p.118 L.4-9]. Dr. Stormont further indicated that the cows in his test group still produced the isoantibodies over a year after their last booster injection [App. p.118 L.10-23]. This testimony clearly shows that the witnesses had some conflicting opinions and by the preponderance of evidence that Anaplaz caused N.I. in the Haste herd.

Other evidence that Anaplaz causes N.I. was produced by the Plaintiffs in the form of papers. The Court App. p. 16

should read, for example, Exhibits No. 53 [Ex. p.10]; Exhibit No.54 [Ex. p.15]; Exhibit No. 55 [Ex.p.19]; Exhibit No. 58 [Ex. p.20]; Exhibit No. 80, [Ex. p.29]. These articles as well as letters submitted into evidence between Dr. Stormont and American Home Products as well as United States Government directives to the Defendant submitted into evidence more than adequately showed by a preponderance that Anaplaz causes N.I.

Clearly the testing as evidenced by the testimony of Dr. Stormont and Dr. Young was not the subject of speculation on their parts. Their opinions were based on these tests and were competent to a reasonable degree of certainty.

It is unrebutted that the Plaintiffs' calves died of N.I. Dr. Blessing and Dr. Stormont testified to that. A great deal of testimony was given by many witnesses both experts and veterinarians that N.I. was caused by Anaplaz. Dr. Roberts testified for the Defendant and he indicated that he would not recommend Anaplaz because of the danger of N.I. caused by the vaccine. [R.Vol. X, p.55, App. p.132].

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VI. Warnings.

Defendant contends that the conversations between Dr. Roberts and Dr. Humphreys and the Hastes were sufficient to satisfy its duty to warn the Plaintiffs of the risk of N.I. As they noted, these individuals "had no connection whatever with American Home Products ...". It is unclear how the Defendant finds that its duty to warn can be assigned to veterinarians in Wyoming, where these veterinarians never testified to having received any "Dear Doctor" letters from American Home Products regarding the impossible danger of N.I. from Anaplaz vaccination. Dr. Roberts indicated that the knowledge he had about N.I. came from published articles and not from any information disseminated Defendant.

Adequate warning did not issue to the Hastes from the Defendant. The testimony regarding these conversations by Dr. Humphreys and Dr. Roberts was contradicted by the Plaintiffs' recollection of these conversations. Dr. Humphreys minimized any warning that he may have made. Dr. Roberts did not App. p. 18

consider the vaccine to be a prescription drug and therefore he had no "profession-al duty" to do more than order the vaccine which he did. Mrs. Haste testified that Dr. Roberts said only one sentence that indicated he would not use Anaplaz, without any indication as to why:

"When we were at Dr. Roberts' we told him we were thinking about doing this, in fact, had almost decided to do it. He said that if it were he, he wouldn't do it. We said 'Why?' and he said 'Because of the kind of vaccine it is.' And that is all he said. He does not explain a lot and that is every word he said to us." [Rec.Vol. XI P.120-121, App. p. 153-154].

Judge Winner aptly resolved this testimonial conflict in his memorandum opinion:

"I accept plaintiffs' testimony as to the extent of Dr. Roberts' warning, and I do not think that this warning was of a nature to place a reasonable cattleman on notice of realistic risk from use of Anaplaz." [App. p.30]

Not only was there no duty known to the veterinarians to warn on behalf of the Defendant and no evidence of actual notice to them from the Defendant of N.I.

danger, there was obvious conflict as to the extent of the warnings they testified to which was resolved by the trier of fact in favor of the Plaintiffs. This Court has only to read the record of the liability trial to see that Judge Winner had ample testimony upon which to base his determination that any warnings from the doctors were minimal. \*That decision should not now be overturned by this Court on appeal.

The Defendant challenges Judge Winner's determination that:

"There is a duty to warn the rancher of potential risks in the advertising and sales material which promote the sale of the product." [R.Vol. IV, p. 1352, App. p.32].

The Defendant neglects to mention that this product was extensively advertised in cattlemen's magazines. The Plaintiffs first learned of the product from these magazines. These are included in the Record of this case but Judge Winner's citation of certain passages in his brief indicates some of the representations of safety and the lack of any warning of any potential side effect in App. p. 20

this literature:

"Understandably, and justifiably, the advertising is laudatory of Anaplaz, but, in addition to the broad commendatory language, published advertisements say, for example,

'So vaccinations not only protect your cow herd, but your profits from two calf crops as well. With ease, safety and economy.

"Anaplaz" is an inactivated vaccine, incapable of producing disease. It has been scientifically researched, developed and tested by controlled procedures under both laboratory and actual field conditions. Extensive trials have been conducted in herds on widely separated farms and ranches.'

The 'Dear Doctor' letters recognized the risk of N.I. but the material directed to the ultimate purchaser gave no clue that there was any risk. The advertising literature did not mention a release by the United States Department of Agriculture dated December 29, 1969, which said, inter alia:

'Vaccinating brood cows with anaplasmosis vaccine sometimes may cause fatal side-effects in calves, the App. p. 21

U.S. Department of Agriculture cautioned today

Judge Winner was stating what may seem patently obvious to the lay person but not apparently to counsel for the Defendant. The representations to the buyer were such as to induce them to purchase. Known risks were not merely minimized but were ignored stating that the drug was "incapable of producing disease." Surely some burden should be placed on the manufacturer of a product with a known risk to inform potential buyers, before purchase, of that danger.

Exhibit 23 (1) [Memorandum Opinion App. p.29] which is a brochure supplied by the Defendant to Dr. Humphreys and given by him to the Plaintiffs when they inquired about the Anaplaz vaccine assured them that "five years of Anaplaz field use has shown there's no longer any reason for running the risks of suffering the ravages of anaplasmosis." (emphasis added). This same brochure described the vaccine as "safe" and "readily available."

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These overt representations, that uncontrovertedly reached the plaintiffs, were relied on by them in purchasing the vaccine. Any understanding they may have had about a risk as enormous as the one existing here came from others and was minimized by them.

In <u>Stevens vs. Parke Davis and Co.</u>, 507 P.2d 653 (Calif. 197) the question was raised as to the adequacy of a warning given to a physician regarding dangers of a prescription drug for human use. The Supreme Court of California stated:

"Although the manufacturer or supplier of a prescription drug has a duty to adequately warn the medical profession of its dangerous properties or of facts which makes it likely to be dangerous, an adequate warning to the profession may be eroded or even nullified by over-promotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given." (id. at p.661)

If over-promoting a drug to a doctor can be grounds for the nullification of any warnings given him then  $\underline{a}$  App. p. 23

fortiori the same principle should apply to lay persons to whom the drug is directly marketed. Another prescription drug case raised a similar issue making the point that if over-promoting reasonably induces a doctor to disregarding warnings he has received then the warning is withdrawn or cancelled. See Love vs. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183.

The warnings, if any, given by the doctors were in contradiction to the literature read by the Plaintiffs and supplied by the Defendant. This literature assured safety and indicated "no reason" for taking any risk anaplasmosis. The package insert supplied in small print inside the container was insufficient as a warning. sales-pitch of the Defendant could not be overcome by a minimizing technical statement inside the purchased package.

The trial Court's determination that the warnings were inadequate is amply supported by the record and by available case law and should not be overturned.

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VII. Contributory Negligence And Assumption of the Risk.

The Defendant asserts that the Plaintiffs, being fully informed of the possibility of N.I. from Anaplaz vaccine, assumed the risk of their cattle contracting the disease and proceeded to vaccinate. As discussed in the preceding section, the Plaintiffs were certainly not "fully informed" and in fact were misled by the literature published by Defendant that they received.

Defendant indicates that the vaccination of the bulls by the Plaintiffs shows that they were testing the product for future use on the cows evidencing a "calculated risk on their part." It is highly unlikely that a reasonable rancher would test out a product on his most valuable animals. Dr. Humphreys indicated that the reason he vaccinated the bulls at the time he did was because they were in Worland.

"... and when Bill brought down these two bulls, they were his most valuable animals, he decided to use the vaccine on the bulls as he had them down, App. p. 25

he brought them down to Worland, anyway, to have their feet trimmed." p.136 [App. L.5-91.

Since this was the first time Dr. Humphreys recalled mentioning the possibility of N.I., it is unlikely that Mr. Haste "calculated" that risk in vaccinating the bulls. As the counsel for Defendant appropriately noted at the trial, the bulls weren't going to have any calves so any mention the doctor may have made about calves having N.I. would not have indicated any risk as far as the bulls were concerned. Nor would the vaccination of the bulls resolve any "calculation" of risk of N.I. in cows and their calves. Clearly the reason for the vaccination was to protect his "most valuable" animals from anaplasmosis.

Assumption of a risk as distinguished from contributory negligence requires "actual knowledge" of the danger and not constructive knowledge. What was in the mind of the plaintiffs when they purchased the vaccine and vaccinated their cattle is what is important. The Hastes' actions and statements at trial App. p. 26

evidence the fact that they were not actually aware of the severe damage that could occur to their herd. They read the enclosed warning but, as Mr. Haste's testimony reveals regarding the enclosed "warning" on the instruction sheet in the vaccine:

> Well, it minimized the " A . warning end of it to where you wouldn't even consider it.

> In any event you didn't consider it?

> In any event I didn't understand the language to the point where I considered it as any gamble between my calf crop or my cows, because after all I had lost the cows, the big siege, and from there on it was a precautionary measure, and I sure wouldn't have vaccinated my intentionally COWS with something that I knew was gambling the loss of my calf crop on, or the ruination of my cows later." [App. p.147 L.8-17].

In Elder vs. Crawley Book Machine Company, 441 F.2d 771 (3rd Cir. 1971) the Court in an action for personal injuries under strict liability interpreted The Restatement of Torts 2d in its definition of what we call

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assumption of risk as requiring actual knowledge:

"In defining the doctrine, the Restatement makes it clear that the law envisions a conscious appreciation of danger willingness to risk it. comment d, Section 496A says: the distinction theory, between the two (contributory negligence and assumption of risk) is that assumption of risk rests upon the voluntary consent of the Plaintiff to encounter the risk and take his chances ... A subjective standard is applied to assumption of the risk, in determining whether the Plaintiff knows, understands, and appreciates the risk. Comment e, Section 496C states: Assumption of risk is a matter of which Plaintiff knows, understands, and is willing to accept. Comment c, Section 496D states: That the standards to be applied is a subjective one of what the particular Plaintiff in fact sees, knows, understands and appreciates ... . If by reason of age or lack of information, experience, intelligence or judgment, the Plaintiff does not understand the risk involved in a known situation he will not be taken to assume the risk."

1.. applying this subjective standard the Court found that the App. p.28

Plaintiff had not assumed the risk of having her fingers severed by a machine she worked on. Here it is clear from the testimony that what the Plaintiffs saw, understood, and appreciated regarding the vaccine did not include a risk to the calf crop or cows from N.I.

In Ferraro vs. Ford Motor Co., 423 Pa. 324, 223 A.2d 746 (1966), this case involved personal injuries received by the Plaintiff driver of a truck where the Plaintiff knew of the defects in the truck and had several times tried to have the defects fixed by the Defendant, who assured Plaintiff that the condition would correct itself; the Pennsylvania Supreme Court followed the Restatement of Torts 2d, Section 496E comment (a) in reversing a judgment notwithstanding the verdict.

"Comment (a), however, immediately goes on to say: Where, however, the Plaintiff surrenders his better judgment upon an assurance of safety or a promise of protection against the risk, he does not assume it unless a known danger is so extreme that there can be no reasonable reliance upon such an assurance, or unless so much App. p. 29

time has elapsed without action that he can no longer reasonably rely on it.

It is our conclusion that the matrix of logic does not clearly compel the acceptance of only one of those opposing positions. Rather do we believe, that, under the circumstances, reasonable men could honestly differ as to what impact, if any, the dealers assurance would or should have had on the mind of a reasonably prudent automobile driver. Hence, a jury question was presented. We will, therefore, reverse the entry of the notwithstanding judgment verdict." (emphasis added).

In Ralston vs. Illinois Power Co., 299 N.W. 2d 497 (Ill. 1973), it is pointed out that contributory negligence is not a defense to the action of strict products liability and states in regard to assumption of the risk:

"That tests to be resorted to in determining whether one has assumed the risk is fundamentally a subjective test, in the sense that it is his knowledge, understanding, and appreciation of the danger which must be assessed, rather than that of a reasonably prudent person."

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Once again, obviously in the case at bar, the knowledge, understanding and appreciation of the use of the Anaplaz vaccine by the Plaintiffs considering their reliance on Defendant and its product and the inadequate warning was such that they could certainly not be considered to have assumed the risk in any respect as Plaintiff William Haste stated so emphatically, he would do nothing that would endanger his herd, and thus, his livelihood.

In <u>Vernon vs. Lake Motors</u>, 488 P.2d 302 (Utah 1971) the Utah Supreme Court stated:

"If Plaintiff knows of the defect and the danger, but nevertheless 'deliberately and unreasonably' goes ahead, he should be precluded from recovery."

The interpretation of the words, "deliberately" and "unreasonably" are important. Whether the Plaintiffs knew of the danger was also at issue in this case.

Judge Winner rejected assumption of the risk and contributory negligence on the basis of a failure of evidence and

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not because he did not feel it was a proper defense in this case. [App. p.45 and 46]. Therefore the lengthy argument and case cites by Defendant to the effect that contributory negligence and assumption of risk are proper defenses in cases of this nature is not rebutted either by the trial Courts ruling or this brief.

## VIII. Limitation of Implied Warranty

The uniform commercial code as enacted in Wyoming indicates that for implied warranties to be excluded the exclusion must be in writing and conspicuous. The proper language being "There are no warranties which extend beyond the description on the face hereof." W.S. §34-2-316.

The warranties in this case were written in the brochures and literature of the Defendant as indicated in previous sections of this brief. The container itself contained no modifying language but only a referral to enclosures.

The reason for requiring the product to have cautionary statements and warnings printed on the container is to insure that sales contracts are fully App. p. 32

informed. To give a disclaimer after the sale has occured will not protect the seller from his written warranties given in advertising prior to the sale.

## IX. Unusual Susceptibility

The Defendant asserts that since the Hastes were experienced breeders of Santa Gertrudis cattle and the warning contained in the package of vaccine notified them that N.I. occured in another cross-breed, Charolais, in 75% of the reported cases, that they assumed the risk of vaccinating their Santa Gertrudis cattle (another cross-breed). Surely if the Hastes should be held to foresee the danger to their cattle, then the particular susceptibility of their cattle was not unforeseeable to the manufacturer of the product with the weight of scientific development and experimentation behind it.

There was no testimony presented that the risk of N.I. was not known to the Defendant. Indeed, Dr. Searl's testimony and all the literature presented as well as the package insert indicates that it was known to the Defendant that certain cases of N.I. had been reported

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after use of Anaplaz.

The extent of occurrence in the Haste herd is not the correct gauge for foreseeability. Which cattle will contract N.I. at one place is not required to be foreseeable, only the occurrence need be foreseeable, which it clearly was.

## CONCLUSION

The Defendant appeals the finding of liability in this case basically on a theory of a failure of evidence. The record is full of causation evidence and evidence of warranties of safety and evidence of reliance by the Plaintiffs. The trial Courts' liability decision is amply supported by relevant testimony and exhibits and should not be overturned by this Court.

The Damages Judgment should be increased or remanded as set out in the opening brief of Plaintiffs.

Respectfully submitted,

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BY:

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## CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing Reply Brief was served by mailing, postage prepaid this 15th day of August, 1977, to the following:

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